



To: Presidents/Chief Executive Officers of Current and Applicant Medicare Advantage Organizations, Medicare Cost-based Plans and Health Plan Demonstrations, and other interested parties

From: Patricia Smith, Director, Medicare Advantage Group

Subject: Issuance of Draft 2006 Marketing Guidelines for Medicare Advantage Organizations, Cost-based Plans and Health Plan Demonstrations

Comments must be received no later than 11:59 P.M. EDT, May 24, 2005. Submit comments via email to CMS MMAFAQ@cms.hhs.gov

Date: May 12, 2005

We are today issuing draft guidelines for 2006 Medicare Advantage organizations, Medicare cost-based plans, and Medicare health plan demonstrations for public comment. These guidelines constitute Chapter 3 of the Medicare Managed Care Manual.

Comments on these materials must be received no later than 11:59 P.M. EDT, May 24, 2005. Please submit comments via email to CMS MMAFAQ@cms.hhs.gov.

These new guidelines streamline the review of health plan marketing materials by creating a new path to “file and use” status. CMS has effectively used a “file and use” process for marketing materials for a number of years, and the Federal Employees Health Benefit Program relies heavily on a “file and use” approach to marketing materials.

The new “File and Use Certification” process asks Medicare Advantage organizations, health plan demonstrations, and Medicare cost-based plans to certify the accuracy of certain marketing materials. The certification by a senior plan official enables the health plan to begin market distribution of applicable materials 5 calendar days after they are submitted to CMS. Thus, the “File and Use Certification” process will reduce the time that it takes for health plans to put their marketing materials into the marketplace. Please note that certain core documents such as the Summary of Benefits, Evidence of Coverage, and Annual Notice of Change, will continue to be reviewed by CMS in their entirety before they may be used for marketing.

The draft materials describe the revised streamlined marketing review process as outlined below.

- File and Use Certification – All organizations are now strongly encouraged to use the new “File and Use Certification” process. This process allows organizations to begin market distribution of certain marketing materials 5 calendar days after they have been submitted

to CMS. This process draws on the competition of the marketplace to help ensure that beneficiaries receive accurate information, in much the same way as is done in the Federal Employees Health Benefit program. "File and Use Certification" requires that the CEO or CFO of the organization certify that the materials meet CMS requirements. Organizations that choose not to use the Certification process, must notify their CMS Regional Office that they are requesting to waive their use of the "File and Use Certification" process. Please note that the Certification or waiver request needs to be submitted to CMS no later than July 1, 2005.

- File and Use Eligibility – A number of organizations have already attained "File and Use Eligibility" status. These organizations may continue to submit materials under their "File and Use Eligibility" status, or they may choose to follow the new "File and Use Certification" process. If a "File and Use Eligible" organization chooses to use "File and Use Certification," it will not lose its "File and Use Eligible" status.

Organizations may qualify for "File and Use Eligibility" after they have been in the Medicare Advantage program for at least 18 months and their marketing materials have been found to be at least 90% "acceptable" in the last 6 months. Eligibility status permits a plan to submit certain marketing materials under "File and Use Eligibility." (See Medicare Managed Care Manual, Chapter 3, section 20.5).

- Intensive Review – Organizations must continue to submit core documents, such as the Summary of Benefits, Evidence of Coverage, Member Handbook, Annual Notice of Change, Mid-Year Benefit Enhancement Notices, and Enrollment and Disenrollment forms, for intensive 45/10-day review as outlined in Section 422.80 of the Medicare regulations and in Chapter 3 of the Medicare Managed Care Manual. The File and Use Certification process cannot be applied to these documents. We are applying this intensive review to ensure the accuracy and clarity of these marketing materials in order to facilitate Medicare beneficiaries understanding of their benefits. Moreover, these materials are the foundation upon which many other marketing materials are built.
- Model materials – We continue to make available model language for many marketing materials, such as enrollment and disenrollment notices, notices related to failure of the beneficiary to pay the plan premium, and appeal and grievance forms and letters. Use of model materials for marketing documents that are subject to the intensive review process enables an organization to gain approval within 10 days of filing these documents with CMS.

The following documents are included with this release. Attachment 3 provides detailed information on which level of marketing review is required for different types of materials.

- Attachment 1 – File and Use Certification Process
- Attachment 2 – File and Use Certification Matrix
- Attachment 3 – Marketing Category Description
- Attachment 4 – Transmittal Change Summary
- Attachment 5– Draft of Chapter 3, Medicare Managed Care Manual
- Attachment 6 – Marketing Timeline

Comments on these draft documents must be received in writing, but if you have questions during this comment period, please contact Robin Magwood at 410-786-1999 or you may use the e-mail box at [CMS MMAFAQ@cms.hhs.gov](mailto:CMS_MMAFAQ@cms.hhs.gov).

Again, thank you for your ongoing efforts to transition to the new requirements of the Medicare Modernization Act. We look forward to your comments on the revised Marketing Guidelines.